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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,214	03/20/2001	Kenneth Tucker	7969-089-999	1989

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EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,214	TUCKER ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-16,19,21,27,29,34,35,40 and 42-56* is/are pending in the application.

4a) Of the above claim(s) *13-16,27,29,35 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,12,19,21,34 and 42-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' amendment, received October 08, 2003, is acknowledged. Claim 34 was amended.

2. Applicants' Affidavit and Declaration under 37 C.F.R. 1.131, received October 08, 2003, is acknowledged. The declaration has been reviewed by the examiner.

Status of the Claims

3. Claims 1-8, 11-16, 19, 21, 27, 29, 34, 35, 40 and 42-56 are pending. Claims 13-16, 27, 29, 35 and 40 are withdrawn from consideration.

4. Claims 1-8, 11-12, 19, 21, 34 and 42-56 are under consideration.

Prior Citations of Title 35 Sections

5. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

6. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 has been submitted with this office action.

Objections Withdrawn

7. Objection to the specification made in paragraph 5 of the office action mailed 4/9/2003 is withdrawn in view of applicants' arguments.

Rejections Withdrawn

8. Rejection of claims 1, 2, 6-8, 11-12, 19, 21, 42-47 and 52-56 under 35 U.S.C. 112, first paragraph, made in paragraph 9 of the office action mailed 4/9/2003 is withdrawn in view of applicants' arguments.

9. Rejection of claims 3, 4 and 34 under 35 U.S.C. 112, second paragraph, made in paragraph 11 of the office action mailed 4/9/2003 is withdrawn in view of applicants' arguments and amendments.

10. Rejection of claims 1-6, 19, 21, 34 and 42, 44, 46, 48, 49, 51, 53-56 under 35 U.S.C. 102(e) as being anticipated by Sasaki et al. (US 6,335,018, US 6,440,425, and US 6,440,424) is withdrawn in view of applicants' declaration. The Declaration filed on October 08, 2003 under 37 CFR 1.131 is sufficient to overcome the Sasaki et al. reference.

Rejections Maintained

11. Rejection of claims 1-8, 11-12, 19, 21, 34 and 42-56 under 35 U.S.C. 101) double patenting made in paragraph 6 of the office action mailed 4/9/2003 is maintained.

12. Rejection of claims 5, 19 and 21 under 35 U.S.C. 101) double patenting made in paragraph 7 of the office action mailed 4/9/2003 is maintained.

13. Rejection of claims 1-8, 11,12, 34 and 42-56 under the judicially created doctrine of obviousness-type double patenting made in paragraph 8 of the office action mailed 4/9/2003 is maintained.

14. Rejection of claims 19, 42-43, 46 -49 and 55-56 under 35 U.S.C. 112, first paragraph, made in paragraph 10 of the office action mailed 4/9/2003 is maintained.

The rejection was as stated below:

Claims 19, 42-43, 46 -49 and 55-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antigenic polypeptide, does not reasonably provide enablement for a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/or use the invention commensurate in scope with these claims.

In the instant case claims 19, 42-43, 46 -49 and 55-56 are drawn to a vaccine. The only given example in the specification is in pages 28-29 mentioning the production of a *Moraxella catarrhalis* vaccine from inactivated or attenuated HA or NHA cultivars of *Moraxella catarrhalis.*

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated base on that limitation. See in re Vaeck, 947 F. 2d 488, 495,20 USPQ 2d 1438, 1444 (Fed Cir, 1991).

Dorland's Medical Dictionary (29th Edition, 2000) defines "vaccine" as "a suspension of attenuated or killed microorganisms (bacteria, viruses, or rickettsiae), or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases. In the instant case the applicants invention is not enabled for the prevention, amelioration, or treatment of infectious diseases. And one skilled in the art will not be able to make/and or use the invention without undue experimentation.

It's unclear from the specification exactly how the vaccine was produced or used. Additionally its unclear what type of immune response was elicited when the preparation was administered and whether or not the response correlated to protective immunity against *Moraxella catarrhalis.*

It is well known in the art that there are several different antigens from *Moraxella catarrhalis* (i.e. outer membrane proteins, lipooligosaccharides). It is also taught that since infections caused by *Moraxella* are predominately occur on mucosal surfaces, the mucosal immune response is likely important as the first line of defense. Mucosal or surface antigen immune response would likely be important in the search for candidate vaccine (Kyd et al. 2000). It has also been recognized in the art that there is currently no vaccine to prevent *Moraxella catarrhalis* infections because of a lack of good animal models for the diseases, a lack of information about the protective antigens, a lack of in vitro correlates to immunity against *Moraxella catarrhalis* in humans and the pathogenic mechanisms and host immune response to the pathogens has yet to be clarified (Chen, et al. 1996; Gu, et al. 1998, Hu et al. 2000; Samukawa, et al. 2000 and kyd, et al. 2000). While studies have shown the outer membrane proteins can elicit bactericidal antibodies, which promote bacterial clearance, the results have not lead to a predictable vaccine against infections caused by *Moraxella catarrhalis*. Clearly a great amount of experimentation would be necessary in order to develop an efficacious vaccine against *Moraxella catarrhalis* infections.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the court of appeals in In re Wands, 8 USPQ 2d 1400 at 1404 (CAFC 1988).

These factors include 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art, and 8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other antigens having claimed functional feature of capability of generating protective responses, 3) there are no working examples which suggest the desired results of a vaccine against *Moraxella catarrhalis*, 4) the nature of the invention involved the complex and incompletely understood area of protective immune responses against *Moraxella catarrhalis* , 5) the state of the prior art shows the lack of correlates to immunity with *Moraxella catarrhalis*, 6) the relative skill of those in the art is commonly recognized as quite high (post – doctoral level), and the lack of predictability in the field to which the invention pertains is recognized in the art as evidenced by the cited prior art.

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the invention commensurate in scope with the claims.

Applicants' arguments filed 10/08/2003 have been fully considered but they are not persuasive.

Applicants argue that the specification section 5.6 entitled " vaccine" teach a vaccine of the present invention comprising an OMP 106 immnuogen and pharmaceutically acceptable carrier.

It is the examiner's position that it is still unclear from the specification exactly how the vaccine was produced or used. Additionally it is unclear what type of immune response was elicited when the preparation was administered and whether or not the response correlated to protective immunity against *Moraxella catarrhalis.* As mentioned above the specification, while

being enabling for an antigenic polypeptide, does not reasonably provide enablement for a vaccine.

15. Rejection of claim 1 as originally filed and as presently pending, (and claims 2-8, 11-12, 19, 21, 34 and 42-56 dependant thereon) under 35 U.S.C. 112, second paragraph, made in paragraph 11 of the office action mailed 4/9/2003 is maintained.

The term "substantially" in claims 1 is a relative term, which renders the claim indefinite. The term " substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

16. Claims 1-8, 11-12, 19, 21, 34 and 42-56 stand rejected.

17. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The

examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

January 6, 2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER